

REMARKS

This Amendment is filed in response to the Final Office Action mailed December 27, 2010 ("*Final Office Action*"). In this Amendment, claim 23 is amended. Claims 24-28, 40, and 41 are unchanged. Claims 29-39 were previously withdrawn, and claims 1-22 were previously canceled. Following entry of this amendment, claims 23-28, 40, and 41 shall be pending.

In the *Final Office Action*, claims 23-28, 40 and 41 are rejected based on prior art grounds. For the reasons set forth below, these rejections are hereby traversed.

I. REJECTIONS UNDER 35 U.S.C. § 103

Claims 23-28, 40, and 41 are rejected under 35 U.S.C. § 103(a) as being obvious by U.S. Patent No. 6,231,597 to Deem et al. ("*Deem*") in view of U.S. Patent No. 6,309,367 to Boock ("*Boock*"). Of these claims, claims 23 and 40 are independent claims. Claims 24-28 are dependent claims that depend from claim 23, and claim 41 is a dependent claim that depends from claim 40. For at least the reasons set forth below, it is submitted that these prior art rejections should be withdrawn and the pending claims allowed.

Without conceding to the merits of the rejections, claim 23 has been amended to recite a device for treating a vascular aneurysm comprising: a support structure sized for placement at a region of said vascular aneurysm; said support structure having a bridge portion spanning at least a neck region of said vascular aneurysm; said support structure having an open, non-tubular arced configuration; said bridge portion including a reactive material, said reactive material being volumetrically expanded when in a reacted state such that said bridge portion restricts flow of blood to said vascular aneurysm when said reactive material is in said reacted state.

Claim 40 has not been amended and recites an implant for treating a vascular aneurysm comprising: an implant body sized to reside at a region of said vascular aneurysm; said implant body having an occlusion region that substantially traverses a

neck region of said vascular aneurysm; said implant body having an arc shape, said arc shape having a sweep less than 360 degrees; said occlusion region including a reactive material, said reactive material being volumetrically expanded when in a reacted state such that said occlusion region substantially restricts flow of blood to said vascular aneurysm when said reactive material is in a reacted state.

In the *Final Office Action*, the Examiner asserted that it would have been obvious to one having ordinary skill in the art at the time the invention was made to have included the swellable polymer bit 94 of *Boock* on the mid-region 15 of the stent taught by *Deem* and, apparently, that this proposed modification makes obvious the claimed reactive material being expandable when in a reacted state such that the bridge portion (claim 23) or the occlusion region (claim 40) substantially restricts flow of blood to said vascular aneurysm when said reactive material is in said reacted state. These rejections are improper for at least two reasons.

First, the rejections fail to properly consider the claimed invention as a whole as required by the M.P.E.P. Section 2141.02(I) of the M.P.E.P. states that "[i]n determining the differences between the prior art and the claims, the question under 35 U.S.C. 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious." Considering the claimed invention as a whole, independent claims 23 and 40 recite the reactive material being expandable when in a reacted state such that the bridge portion (claim 23) or the occlusion region (claim 40) substantially restricts flow of blood to said vascular aneurysm when said reactive material is in said reacted state, i.e. there is a causal relationship between the reactive state of the reactive material and the flow restriction characteristics of the bridge or occlusion region. These claimed features are neither addressed in the rationale provided for the rejections in the *Final Office Action* nor taught or made obvious by the cited prior art.

For example, as previously held by the Board of Patent Appeals and Interferences and restated by the Examiner in the *Final Office Action*, the mid-region 15 and cover 102

of the stent of *Deem* fail to teach a volumetrically expandable reactive material. Similarly, *Boock* fails to teach or make obvious that the main body 90 is in any way reactive. With respect to the swellable polymer bit 94, *Boock* teaches that:

One embodiment illustrated at 90 and FIG. 13 includes an aneurysm shield main body 92, with a swellable polymer bit 94, that is positioned on an inside surface, facing the aneurysm. The material, such as is shown in FIG. 14, swells, and **the polymer or similar material fills the neck of the aneurysm beyond the shield**, further sealing and supporting the shield. **The use of the polymer positioned at the neck of an aneurysm acts as a secondary aneurysm closure.** The polymer may have a swell ratio of 2:1 to 100:1 and swells by absorption of water over time **to form a secondary foam plug and to add further closure** and mechanical support at the neck of the aneurysm.

Col. 4, lines 15-27 (Emphasis added). As would be understood by one of ordinary skill in the art based upon the above, the swellable polymer bit 94 is an independent appendage that projects outward from the main body 92. *Id.* In other words, its purpose is to fill and plug the aneurysm, not to provide a flow restriction characteristic to the main body 92 itself *Id.*

Hence, including the swellable polymer bit 94 of *Boock* on the mid-region 15 of the stent taught by *Deem*, as proposed by the Examiner, would do nothing to the flow restriction characteristics of the mid-region 15 at the stent of *Deem*. It simply would serve as a plug, in and of itself, to the aneurysm. As such, the cited prior art fails entirely to teach or suggest a relationship between the bit 94 and the flow restriction characteristics of the mid-region 15 of the *Deem* stent or, for that matter, the main body 90 of *Boock*.

Second, the present rejections are improper because the Examiner's proposed modifications would improperly modify the principle of operation of the stent of *Deem*. Section 2143.01 VI of the M.P.E.P. states, "[i]f the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious." The purpose of the stent of *Deem* is to obstruct flow to an

aneurysm while simultaneously minimizing obstruction of flow through the healthy vessel. Col. 5, lines 18-22. The principle of operation of the stent taught by *Deem* is simply to ***span the neck of the aneurysm***, by deployment of the stent at the site of interest and orientation of the mid-region 15 across the opening of the vascular abnormality and NOT to plug the aneurysm. Col. 5, lines 45-54. As provided above, the swellable polymer bit 94 of *Boock* extends outward from the main body 92. Col. 4, lines 15-27. In other words, the swellable polymer bit 94 functions to form a ***plug that fills the neck of the aneurysm***. *Id.* It does not address the flow characteristics of the main body 92 itself.

Hence, including the swellable polymer bit 94 of *Boock* on the mid-region 15 of the stent taught by *Deem*, as proposed by the Examiner, would change the stent of *Deem* from a device that simply spans the neck of an aneurysm to a device that both spans the neck of an aneurysm and extends into and plugs the aneurysm. One of ordinary skill in the art would recognize that this is not a trivial change in the principle of operation of the stent 10 of *Deem*. For example, the Examiner's proposed modification would require increased customization of the device in order to properly fit the device not only to the dimensions of the patient's vessel but also to the dimensions of the neck of the patient's aneurysm. The proposed modified device would also require significantly greater precision during deployment of the device in order to deploy the device such that the swellable polymer bit is properly aligned with the neck of the aneurysm into which it will expand. Misalignment of the swellable polymer bit 94 of the proposed device would, in contrast to the purpose of the stent of *Deem*, likely result in ***increased obstruction*** of the flow through the healthy vessel, as well as an increased likelihood of potential damage to the vascular abnormality.

In view of the above, it becomes evident that the present rejections are improper and that *Deem* in view of *Boock* fails to teach or make obvious the present invention as claimed in independent claims 23 and 40. Hence, withdrawal of these rejections and an indication of allowance are respectfully requested.

Turning to claims 24-28 and 41, these claims depend from independent claim 23 or 40 and are allowable for at least the same reasons as claims 23 and 40. However, these claims further limit the claimed invention and thus are separately patentable over the cited prior art.

II. RELATED APPLICATIONS OF ASSIGNEE

Applicant wishes to draw the Examiner's attention to the following related applications of the present application's assignee.

Docket No.	Serial No.	TITLE	Filed
020/DE	547530	INTRAVASCULAR HYDROGEL IMPLANT	12/12/1992
020/EPO	92121203.1	INTRAVASCULAR HYDROGEL IMPLANT	12/12/1992
020/ES	547530	INTRAVASCULAR HYDROGEL IMPLANT	12/12/1992
020/FR	547530	INTRAVASCULAR HYDROGEL IMPLANT	12/12/1992
020/IT	547530	INTRAVASCULAR HYDROGEL IMPLANT	12/12/1992
020/UK	547530	INTRAVASCULAR HYDROGEL IMPLANT	12/12/1992
020A/US	07/809,265	INTRAVASCULAR HYDROGEL IMPLANT	12/16/1991
023/C	09/758,832	INSITU FORMABLE AND SELF-FORMING INTRAVASCULAR FLOW MODIFIER (IFM, CATHETER AND IFM ASSEMBLY, AND METHOD FOR DEPLOYMENT OF SAME	01/11/2001
023/EP	97930198.3	INSITU FORMABLE AND SELF-FORMING INTRAVASCULAR FLOW MODIFIER (IFM, CATHETER AND IFM ASSEMBLY, AND METHOD FOR DEPLOYMENT OF SAME	06/19/1997
023A/US	08/668,229	INSITU FORMABLE AND SELF-FORMING INTRAVASCULAR FLOW MODIFIER (IFM, CATHETER AND IFM ASSEMBLY, AND METHOD FOR DEPLOYMENT OF SAME	006/21/1996
023C2	11/107,600	INSITU FORMABLE AND SELF-FORMING INTRAVASCULAR FLOW MODIFIER (IFM, CATHETER AND IFM ASSEMBLY, AND METHOD FOR DEPLOYMENT OF SAME	04/15/2005
033/EPO	4759007	METHODS AND APPARATUS FOR TREATING ANEURYSMS AND OTHER VASCULAR DEFECTS	03/25/2004

Docket No.	Serial No.	TITLE	Filed
033/JP	2006-509415	METHODS AND APPARATUS FOR TREATING ANEURYSMS AND OTHER VASCULAR DEFECTS	03/25/2004
033/PCT	PCT/US2004/009528	METHODS AND APPARATUS FOR TREATING ANEURYSMS AND OTHER VASCULAR DEFECTS	03/25/2004
033A/US	10/400,138	METHODS AND APPARATUS FOR TREATING ANEURYSMS AND OTHER VASCULAR DEFECTS	03/25/2003
033B	11/678,544	METHODS AND APPARATUS FOR TREATING ANEURYSMS AND OTHER VASCULAR DEFECTS	02/23/2007
057A	09/909,715	ANEURYSM TREATMENT DEVICE AND METHOD OF USE	07/20/2001
057A/DIV	12/510,548	ANEURYSM TREATMENT DEVICE AND METHOD OF USE	07/28/2009
057/AU	2002316320	ANEURYSM TREATMENT DEVICE AND METHOD OF USE	06/21/2002
057/CA	2455464	ANEURYSM TREATMENT DEVICE AND METHOD OF USE	06/21/2002
057/CN	28185414.5	ANEURYSM TREATMENT DEVICE AND METHOD OF USE	06/21/2002
057/CN/DIV	2.0081E+11	ANEURYSM TREATMENT DEVICE AND METHOD OF USE	06/21/2002
057/EPO	2746613.5	ANEURYSM TREATMENT DEVICE AND METHOD OF USE	06/21/2002
057/AT	2746613.5	ANEURYSM TREATMENT DEVICE AND METHOD OF USE	06/21/2002
057/FR	2746613.5	ANEURYSM TREATMENT DEVICE AND METHOD OF USE	06/21/2002
057/DE	2746613.5	ANEURYSM TREATMENT DEVICE AND METHOD OF USE	06/21/2002
057/IT	2746613.5	ANEURYSM TREATMENT DEVICE AND METHOD OF USE	06/21/2002
057/ES	2746613.5	ANEURYSM TREATMENT DEVICE AND METHOD OF USE	06/21/2002
057/UK	2746613.5	ANEURYSM TREATMENT DEVICE AND METHOD OF USE	06/21/2002
057/EPO/DIV	8018517.6	ANEURYSM TREATMENT DEVICE AND METHOD OF USE	06/21/2002

Docket No.	Serial No.	TITLE	Filed
057/EPO/DIV2	EP10182994.3	ANEURYSM TREATMENT DEVICE AND METHOD OF USE	06/21/2002
057/EPO/DIV3	EP10183028	ANEURYSM TREATMENT DEVICE AND METHOD OF USE	06/21/2002
057/JP	2003-513435	ANEURYSM TREATMENT DEVICE AND METHOD OF USE	06/21/2002
057/JP/DIV	2007-207873	ANEURYSM TREATMENT DEVICE AND METHOD OF USE	06/21/2002
057/PCT	PCT/US2002/019676	ANEURYSM TREATMENT DEVICE AND METHOD OF USE	06/21/2002
057/BR	P10211281-7	ANEURYSM TREATMENT DEVICE AND METHOD OF USE	06/21/2002
058B/AU	2005208722	ANEURYSM TREATMENT DEVICE AND METHOD OF USE	01/20/2005
058B/AU/DIV	2010249161	ANEURYSM TREATMENT DEVICE AND METHOD OF USE	01/20/2005
058B/PCT	PCT/US2005/001621	ANEURYSM TREATMENT DEVICE AND METHOD OF USE	01/20/2005
058B/CA	2553611	ANEURYSM TREATMENT DEVICE AND METHOD OF USE	01/20/2005
058B/CN	2.0058E+11	ANEURYSM TREATMENT DEVICE AND METHOD OF USE	01/20/2005
058B/EPO	5711629.5	ANEURYSM TREATMENT DEVICE AND METHOD OF USE	01/20/2005
058B/JP	2006-551219	ANEURYSM TREATMENT DEVICE AND METHOD OF USE	07/24/2006
058B/US	10/763,975	ANEURYSM TREATMENT DEVICE AND METHOD OF USE	01/22/2004
059B	10/892,884	ANEURYSM TREATMENT DEVICE AND METHOD OF USE	7/106/2004
504	12/146/252	SELF-EXPANDING PROSTHESIS	06/25/2008
504/PCT	PCT/US2008/068210	SELF-EXPANDING PROSTHESIS	06/25/2008
504/CA	2704920	SELF-EXPANDING PROSTHESIS	06/25/2008
504/CN	200880104160.3	SELF-EXPANDING PROSTHESIS	06/25/2008
504/EP	08771949.8	SELF-EXPANDING PROSTHESIS	06/25/2008
504/JP	2010-515085	SELF-EXPANDING PROSTHESIS	06/25/2008

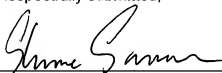
CONCLUSION

In view of the foregoing, it is submitted that pending claims 23-28, 40, and 41 are now in condition for allowance. Hence, an indication of allowability is hereby requested.

If for any reason direct communication with Applicants' attorney would serve to advance prosecution of this case to finality, the Examiner is cordially urged to call the undersigned attorney at the below listed telephone number.

The Commissioner is authorized to charge any additional fee which may be required in connection with this Amendment to deposit account No. 50-2809.

Respectfully submitted,



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